

**REMARKS**

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claims 2, 4, and 9-11 have been amended, so that claims 2-4 and 9-11 will remain pending upon entry of the present amendment.

The specification stands objected to based on informalities relating to lacking a brief description of the drawings and an awkwardly worded title. This objection is respectfully traversed.

The title has been amended to recite "COMPOSITION AND A METHOD FOR TREATING HAIR LOSS" which more precisely describes the invention.

Regarding the lack of a brief description of the drawings, the Examiner's attention is directed to the Preliminary Amendment filed July 22, 2004, in the present application. Page 2 of that amendment sets forth additions to the specification which include a heading and text for a brief description of the drawings.

Accordingly, withdrawal of the record objection to the specification is respectfully requested.

Claim 10 stands objected to for not ending in a period and lacking the word "and" between the last two recited members of the composition. Accordingly, claim 10 has been amended to correct the noted deficiencies and withdrawal of the record objection to claim 10 is respectfully requested.

Claims 2-4 and 9-11 stand rejected under 35 U.S.C. § 101 based on the invention lacking patentable utility. This rejection is respectfully traversed.

Independent claims 2, 9, and 11 have been amended to recite "a method for treating hair loss resulting from telogenic defluvium" which sets forth the purpose for which the method is practiced. Accordingly, the claims set forth a specific utility and withdrawal of the record rejection under 35 U.S.C. § 101 is respectfully requested.

Claims 2-4 and 9-11 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. This rejection is respectfully traversed.

Independent claims 2, 9, and 11 have been amended to recited "a method for treating hair loss resulting from telogenic defluvium" to particularly point out and distinctly claim to what effect the method is being practiced.

Moreover, claims 2, 9, and 11 have been amended to replace the term “combat” with the term “treat.”

Claim 4 has been amended to change the term “robust” and insert the phrase “improved in strength and general health.” Support for this amendment can be found in the specification at least at page 7, lines 19-25. Accordingly, no new matter has been presented by entry of this subject matter. Withdrawal of the record rejection under 35 U.S.C. § 112, second paragraph, in view of the above-noted amendments is respectfully requested.

Claims 2-4, 9, and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Rinaldi. This rejection is respectfully traversed.

The cited Rinaldi reference is a 2002 article from *Cosmetic Technology* (2002, 5(6), 9-15). This article is indicated as being published in the November/December issue of 2002 (see the left margin along the cover page of the Journal, (6) 2002 November/December indicating the last (6) bimonthly issue of the year). Thus, this article was published after the February 1, 2002, filing of the priority document of the present application. Enclosed herewith is a verified English language translation of the priority document and a Declaration stating that the translation of the certified copy is accurate. A review of the text of the verified translation reveals 35 U.S.C. § 112 support for claims 2-4, 9, and 11 of the present invention. Accordingly, applicants are entitled to the priority date and the cited Rinaldi reference is not prior art to the present invention.

Withdrawal of the record rejection of claims 2-4, 9, and 11 under 35 U.S.C. § 102(b) as being anticipated by Rinaldi is respectfully requested.

Claims 2-4, 9, and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by OTC (“Dietary Supplements Market in Italy;” abstract cited PTO-892, 3/2/06), as evidenced by Rinaldi. This rejection is respectfully traversed.

Applicants submit that claims 2-4, 9, and 11 are not anticipated by Dietary supplements marketed in Italy in 1992, namely, Bioscalin since identification of a product name is not an adequate disclosure of each and every element of the claimed invention. There is no identification of the components in the 1992 product. Reference to the brand name of a product in a later 2002 publication (Rinaldi) is not sufficient evidence to establish the components of the earlier 1992 product. As recognized by the USPTO, a trademark or trade name cannot be used properly to identify any particular material or product. The formula or characteristics of the product may change from time to time and yet it may

continue to be sold under the same trademark. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. *See* MPEP 608.01(v), 706.03(d).

Moreover, Applicants submit the following evidence that the composition of Bioscalin in the 1992 product did not contain spermidine. Enclosed herewith is a copy of the packaging for the 1992 product Bioscalin (Retard) which does not contain spermidine in the list of ingredients. Even without translating into English, it can easily be seen that the ingredients have Italian names quite similar to the English version (except for Grassi, which means Fats) none of which is spermidine. Carboidrati is Carbohydrates, while all the rest appears to be easily recognized. "Valore energetico" refers to the calories, not to the ingredients. Spermidine is nowhere to be found on the packaging listing among the many ingredients mentioned therein (multivitamins, minerals, etc).

The USPTO has failed to provide any direct evidence that the 1992 product mentioned in the OTC 2002 publication by trademark name only, actually contained spermidine. Accordingly, withdrawal of the record rejection under 35 U.S.C. § 102(b) as being anticipated by OTC ("Dietary Supplements Market in Italy;" abstract cited PTO-892, 3/2/06), as evidenced by Rinaldi and allowance of claims 2-4, 9, and 11 is respectfully requested.

Claims 2-4 and 11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Falk (US 2003/0118591 A1). This rejection is respectfully traversed.

The undersigned notes that the cited Patent Application Publication No. US 2003/0118539 relates to Fahl et al. and assumes that the reference to Falk is merely a typographical error.

There are different types of hair loss, such as androgenic alopecia, alopecia areata, chemotherapy-induced alopecia, cicatricial alopecia, traumatic alopecia, and more, each caused by different reasons. The instant application is specifically concerned with the type classified as telogenic defluvium. The claims are specifically directed to the type of hair loss defined as telogenic defluvium, which is different from androgenic alopecia, or cicatricial alopecia, or alopecia areata, or traumatic alopecia, or chemotherapy-induced alopecia.

The diagnosis of telogenic defluvium is made by taking into consideration the growth phases of the hair. When the anagenic and telogenic phases are altered (and this may take place in both senses: either they are excessively faster or excessively slower than normal), this results in the phenomenon of telogenic defluvium.

As the specification indicates, telogenic defluvium is caused by the following situation. Every day hairs normally die and, under normal conditions, are replaced by new ones since the follicles have synchronized growth cycles. When causes such as psychological stress, metabolic problems, hormone diseases, pregnancy or deficiencies in specific nutrients intervene to upset the equilibrium of follicle life conditions and hair growth, the follicles in the anagen phase may pass directly to the telogen phase causing an early hair loss, i.e. the telogenic hair loss.

Fahl relates to a different type of hair loss, that is, chemotherapy-induced alopecia. As the specification of Fahl recites, this is essentially due to intoxication: the phenomenon of chemotherapy-induced alopecia is believed to result from cytotoxic and apoptosis-related damage to the hair follicle. The pathobiologic mechanisms that underlie chemotherapy induced follicle damage are characterized by bulging of the dermal papilla, kinking and distension of the follicular canal and disruption of the melanogenic apparatus.

Thus, it is not correct to believe, as the Examiner does, that "in treating an individual with alopecia, one is necessarily treating an individual with telogenic defluvium". Due to their different causes, there is no predictability whatsoever that what is active towards one type of hair loss can be active towards another. A well known case is androgenic alopecia, which could not be cured by an agent active against telogenic hair loss. As to Fahl, should a patient suffering from cancer refrain from chemotherapy treatment, chemotherapy-induced alopecia would stop. This would not happen with telogenic defluvium, unless a curative agent is administered such as that described in the present application.

Moreover, the priority date of the present application predates the August 7, 2002 filing date of Fahl et al.

Accordingly, withdrawal of the record rejection under 35 U.S.C. § 102(e) as being anticipated by Fahl (US 2003/0118591 A1) and allowance of claims 2-4 and 11 is respectfully requested.

Claims 2-4 and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Larsen. Claims 2-4, 9, and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Phillips. Each of these rejections is respectfully traversed.

Independent claims 2, 9, and 11 have been amended to recite the purpose of the method cited therein and therefore distinguish both the Larsen and Phillips references as suggested by the Examiner. Withdrawal of each of the record rejections under 35 U.S.C. § 102(b) as being anticipated by Larsen or Phillips is respectfully requested.

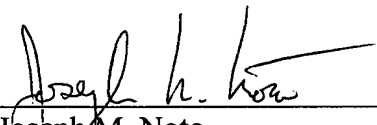
Claims 2-4 and 9-11 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 5-8 of co-pending application No. 11/445,776. This rejection is respectfully traversed.

The co-pending application No. 11/445,776 directed to claims 5-8 was filed as a result of a restriction requirement issued by the Office in the present application on September 29, 2005. However, a double-patenting rejection cannot be sustained over claims that have been restricted by the Office. *See* MPEP 804.01.

Withdrawal of the record rejection of claims 2-4 and 9-11 for double patenting is respectfully requested.

Examination of all the claims of record is next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

  
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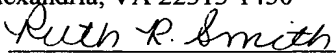
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March 6, 2007

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